



CERTIFICATE OF ACCREDITATION

This is to attest that

CSA GROUP JAPAN

5-40-6 KOISHIKAWA
TOKYO, 112-0002, JAPAN

Testing Laboratory TL-685

has met the requirements of AC89, *IAS Accreditation Criteria for Testing Laboratories* as well as the *FDA ASCA Pilot specifications* and has demonstrated compliance with ISO/IEC Standard 17025:2017, *General requirements for the competence of testing and calibration laboratories*. This organization is accredited to provide the services specified in the scope of accreditation.

Effective Date January 22, 2021



A handwritten signature in black ink, reading "Raj Nathan".

President

SCOPE OF ACCREDITATION

International Accreditation Service, Inc.

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CSA GROUP JAPAN

Contact Name John Chuang

Contact Phone +886 2 2798 7123

Accredited to ISO/IEC 17025:2017

Effective Date January 22, 2021

FDA ASCA Pilot Program

FDA ASCA Pilot Program Scope

Basic Safety and Essential Performance of Medical Electrical Equipment, Medical Electrical Systems and Laboratory Medical Equipment	
ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text)	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD)
IEC 60601-1-3 Edition 2.1 2013-04	Medical electrical equipment - part 1-3: general requirements for basic safety and essential performance - collateral standard: radiation protection in diagnostic x-ray equipment
IEC 60601-1-6 Edition 3.1 2013-10	Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability
IEC 60601-1-6 Edition 3.2 2020-07 CONSOLIDATED VERSION	Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability
IEC 60601-2-18: Edition 3.0 2009-08	Medical electrical equipment - part 2-18: particular requirements for the basic safety and essential performance of endoscopic equipment
IEC 60601-2-22 Edition 3.1 2012-10	Medical electrical equipment - part 2-22: particular requirements for the basic safety and essential performance of surgical cosmetic therapeutic and diagnostic laser equipment
IEC 60601-2-28 Edition 2.0 2010-03	Medical electrical equipment - part 2-28: particular requirements for the basic safety and essential performance of x-ray tube assemblies for medical diagnosis
IEC 60601-2-28 Edition 3.0 2017-06	Medical electrical equipment - part 2-28: particular requirements for the basic safety and essential performance of x-ray tube assemblies for medical diagnosis
IEC 60601-2-33 Ed. 3.2 b:2015	Medical electrical equipment - part 2-33: particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis
IEC 60601-2-37 Edition 2.1 2015	Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment
IEC 60601-2-43 - Ed. 2.0 2010-03	Medical electrical equipment - part 2-43: particular requirements for the basic safety and essential performance of X-ray equipment for interventional procedures

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IEC 60601-2-43 Edition 2.1 2017-05 CONSOLIDATED VERSION	Medical electrical equipment - part 2-43: particular requirements for the basic safety and essential performance of X-ray equipment for interventional procedures
IEC 60601-2-43 Edition 2.2 2019-10 CONSOLIDATED VERSION	Medical electrical equipment - part 2-43: particular requirements for the basic safety and essential performance of X-ray equipment for interventional procedures
IEC 60601-2-44 Edition 3.2: 2016	Medical electrical equipment - part 2-44: particular requirements for the basic safety and essential performance of x-ray equipment for computed tomography
IEC 60601-2-45 Edition 3.1 2015	Medical electrical equipment - part 2-45: particular requirements for basic safety and essential performance of mammographic x- ray equipment and mammomographic stereotactic devices
IEC 60601-2-54 Edition 1.1 2015-04 CONSOLIDATED VERSION	Medical electrical equipment - part 2-50: particular requirements for the basic safety and essential performance of infant phototherapy equipment
IEC 60601-2-54 Edition 1.2 2018-06 CONSOLIDATED VERSION	Medical electrical equipment - part 2-50: particular requirements for the basic safety and essential performance of infant phototherapy equipment
IEC 61010-1 Edition 3.1 2017-01	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements

Regular Scope

Electrical and Electronics	
ANSI/AAMI ES60601-1	Medical electrical equipment— part 1: general requirements for basic safety and essential performance
ANSI/AAMI ES60601-1+ AMD1	Medical electrical equipment— part 1: general requirements for basic safety and essential performance
CAN/CSA C22.2 No. 14	Industrial Control Equipment
CAN/CSA C22.2 No. 60065	Audio, video and similar electronic apparatus - safety requirements
CAN/CSA C22.2 No. 60601-1	Medical electrical equipment - part 1: general requirements for basic safety and essential performance
CAN/CSA C22.2 No. 60601-1+AMD1	Medical electrical equipment - part 1: general requirements for basic safety and essential performance
CAN/CSA C22.2 No. 60601-1-3	Medical electrical equipment - General requirements for basic safety and essential performance - collateral standard: radiation protection in diagnostic x-ray equipment
CAN/CSA C22.2 No. 60601-1-3+AMD1	Medical electrical equipment - General requirements for basic safety and essential performance - collateral standard: radiation protection in diagnostic x-ray equipment
CAN/CSA C22.2 No. 60601-1-6	Medical electrical equipment - part 1-6: general requirements for basic safety and essential performance - collateral standard: usability
CAN/CSA C22.2 No. 60601-1-6+AMD1	Medical electrical equipment - part 1-6: general requirements for basic safety and essential performance - collateral standard: usability

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CAN/CSA C22.2 No. 60601-2-18	Medical electrical equipment - part 2-18: particular requirements for the basic safety and essential performance of endoscopic equipment
CAN/CSA C22.2 No. 60601-2-18+AMD1	Medical electrical equipment - part 2-18: particular requirements for the basic safety and essential performance of endoscopic equipment
CAN/CSA C22.2 No. 60601-2-28	Medical electrical equipment - part 2-28: particular requirements for the basic safety and essential performance of x-ray tube assemblies for medical diagnosis
CAN/CSA C22.2 No. 60601-2-33	Medical electrical equipment - part 2-33: particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis
CAN/CSA C22.2 No. 60601-2-33+AMD1	Medical electrical equipment - part 2-33: particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis
CAN/CSA C22.2 No. 60601-2-33+AMD2	Medical electrical equipment - part 2-33: particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis
CAN/CSA C22.2 No. 60601-2-37	Medical electrical equipment - part 2-37: particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment
CAN/CSA C22.2 No. 60601-2-43	Medical electrical equipment - part 2-43: particular requirements for the basic safety and essential performance of x-ray equipment for interventional procedures
CAN/CSA C22.2 No. 60601-2-43+AMD1	Medical electrical equipment - part 2-43: particular requirements for the basic safety and essential performance of x-ray equipment for interventional procedures
CAN/CSA C22.2 No. 60601-2-44	Medical electrical equipment - part 2-44: particular requirements for the basic safety and essential performance of x-ray equipment for computed tomography
CAN/CSA C22.2 No. 60601-2-44+AMD1	Medical electrical equipment - part 2-44: particular requirements for the basic safety and essential performance of x-ray equipment for computed tomography
CAN/CSA C22.2 No. 60601-2-44+AMD2	Medical electrical equipment - part 2-44: particular requirements for the basic safety and essential performance of x-ray equipment for computed tomography
CAN/CSA C22.2 No. 60601-2-45	Medical electrical equipment - part 2-45: particular requirements for the basic safety and essential performance of mammographic x-ray equipment and mammographic stereotactic devices
CAN/CSA C22.2 No. 60601-2-45+AMD1	Medical electrical equipment - part 2-45: particular requirements for the basic safety and essential performance of mammographic x-ray equipment and mammographic stereotactic devices
CAN/CSA C22.2 No. 60601-2-54	Medical electrical equipment - part 2-54: particular requirements for the basic safety and essential performance of x-ray equipment for radiography and radioscopy
CAN/CSA C22.2 No. 60601-2-54+AMD1	Medical electrical equipment - part 2-54: particular requirements for the basic safety and essential performance of x-ray equipment for radiography and radioscopy
CAN/CSA C22.2 No. 60947-1	Low-Voltage Switchgear and Controlgear – Part 1: General Rules
CAN/CSA C22.2 No. 60947-4-1	Low-Voltage Switchgear and Controlgear – Part 4-1: Contactors and motor-starters-Electromechanical contactors and motor starters
CAN/CSA C22.2 No. 60947-4-2	Low-Voltage Switchgear and Controlgear – Part 4-2: Contactors and motor-starters-AC semiconductor motor controllers and starters
CAN/CSA C22.2 No. 60947-5-1	Low-Voltage Switchgear and Controlgear – Part 5-1: Control circuit devices and switching elements – Electromechanical control circuit devices
CAN/CSA C22.2 No. 60947-5-2	Low-Voltage Switchgear and Controlgear – Part 5-2: Control circuit devices and switching elements – Proximity Switches

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CAN/CSA C22.2 60947-7-1	UL Standard for Safety Low-Voltage Switchgear and Controlgear – Part 7-1: Ancillary equipment – Terminal Blocks for copper conductors
CAN/CSA C22.2 60947-7-2	UL Standard for Safety Low-Voltage Switchgear and Controlgear – Part 7-2: Ancillary Equipment – Protective Conductor Terminal Blocks for Copper Conductors
CAN/CSA C22.2 60947-7-3	UL Standard for Safety Low-Voltage Switchgear and Controlgear – Part 7-3: Ancillary Equipment – Safety Requirements for Fuse Terminal Blocks
CAN/CSA C22.2 60947-7-4	UL Standard for Safety Low-Voltage Switchgear and Controlgear – Part 7-4: Ancillary Equipment – PCB Terminal Blocks for Copper Conductors
CAN/CSA C22.2 No. 60950-1	Information technology equipment - safety - part 1: general requirements
CAN/CSA C22.2 No. 60950-1+AMD1	Information technology equipment - safety - part 1: general requirements
CAN/CSA C22.2 No. 60950-1+AMD2	Information technology equipment - safety - part 1: general requirements
CAN/CSA C22.2 No. 61010-031	Safety requirements for electrical equipment for measurement, control, and laboratory use - part 031: safety requirements for hand-held probe assemblies for electrical measurement and test
CAN/CSA C22.2 No. 61010-1	Safety requirements for electrical equipment for measurement, control, and laboratory use - part 1: general requirements
CAN/CSA C22.2 No. 61010-1+AMD1	Safety requirements for electrical equipment for measurement, control, and laboratory use - part 1: general requirements
CAN/CSA C22.2 No. 61010-2-081	Safety requirements for electrical equipment for measurement, control and laboratory use - part 2-081: particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes
CAN/CSA C22.2 No. 61010-2-101	Safety requirements for electrical equipment for measurement, control and laboratory use - part 2-101: particular requirements for in vitro diagnostic (IVD) medical equipment
CAN/CSA C22.2 No. 62304	Medical device software - software life cycle processes
CAN/CSA C22.2 No. 62304+AMD1	Medical device software - software life cycle processes
CAN/CSA C22.2 No. 62368-1	Audio/video, information and communication technology equipment - part 1: safety requirements
CAN/CSA-IEC 61010-2-201	Safety requirements for electrical equipment for measurement, control, and laboratory use - part 2-201: particular requirements for control equipment
CSA C22.2 No. 55	Special Use Switches
CSA C22.2 No. 65	Wire Connectors
CSA C22.2 No. 188	Splicing Wire Connectors
CSA C22.2 No. 158	Terminal Blocks
IEC/EN 60065	Audio, video and similar electronic apparatus - safety requirements
IEC/EN 60065+AMD1	Audio, video and similar electronic apparatus - safety requirements
IEC/EN 60065+AMD2	Audio, video and similar electronic apparatus - safety requirements
IEC/EN 60601-1	Medical electrical equipment - part 1: general requirements for basic safety and essential performance
IEC/EN 60601-1+AMD1	Medical electrical equipment - part 1: general requirements for basic safety and essential performance
IEC/EN 60601-1-3	Medical electrical equipment - General requirements for basic safety and essential performance - collateral standard: radiation protection in diagnostic x-ray equipment

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IEC/EN 60601-1-3+AMD1	Medical electrical equipment - General requirements for basic safety and essential performance - collateral standard: radiation protection in diagnostic x-ray equipment
IEC/EN 60601-1-6	Medical electrical equipment - part 1-6: general requirements for basic safety and essential performance - collateral standard: usability
IEC/EN 60601-1-6+AMD1	Medical electrical equipment - part 1-6: general requirements for basic safety and essential performance - collateral standard: usability
IEC/EN 60601-2-18	Medical electrical equipment - part 2-18: particular requirements for the basic safety and essential performance of endoscopic equipment
IEC/EN 60601-2-28	Medical electrical equipment - part 2-28: particular requirements for the basic safety and essential performance of x-ray tube assemblies for medical diagnosis
IEC/EN 60601-2-33	Medical electrical equipment - part 2-33: particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis
IEC/EN 60601-2-33+AMD1	Medical electrical equipment - part 2-33: particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis
IEC/EN 60601-2-33+AMD2	Medical electrical equipment - part 2-33: particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis
IEC/EN 60601-2-37	Medical electrical equipment - part 2-37: particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment
IEC/EN 60601-2-37+AMD1	Medical electrical equipment - part 2-37: particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment
IEC/EN 60601-2-43	Medical electrical equipment - part 2-43: particular requirements for the basic safety and essential performance of x-ray equipment for interventional procedures
IEC/EN 60601-2-43+AMD1	Medical electrical equipment - part 2-43: particular requirements for the basic safety and essential performance of x-ray equipment for interventional procedures
IEC/EN 60601-2-44	Medical electrical equipment - part 2-44: particular requirements for the basic safety and essential performance of x-ray equipment for computed tomography
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IEC/EN 60601-2-45	Medical electrical equipment - part 2-45: particular requirements for the basic safety and essential performance of mammographic x-ray equipment and mammographic stereotactic devices
IEC/EN 60601-2-45+AMD1	Medical electrical equipment - part 2-45: particular requirements for the basic safety and essential performance of mammographic x-ray equipment and mammographic stereotactic devices
IEC/EN 60601-2-54	Medical electrical equipment - part 2-54: particular requirements for the basic safety and essential performance of x-ray equipment for radiography and radioscopy
IEC/EN 60601-2-54+AMD1	Medical electrical equipment - part 2-54: particular requirements for the basic safety and essential performance of x-ray equipment for radiography and radioscopy
IEC/EN 60947-1	Low-Voltage Switchgear and Controlgear – Part 1: General Rules
IEC/EN 60947-4-1	Low-Voltage Switchgear and Controlgear – Part 4-1: Contactors and motor-starters-Electromechanical contactors and motor starters

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IEC/EN 60947-4-2	Low-Voltage Switchgear and Controlgear – Part 4-2: Contactors and motor-starters-AC semiconductor motor controllers and starters
IEC/EN 60947-4-3	Low-Voltage Switchgear and Controlgear – Part 4-3: Contactors and motor-starters-AC semiconductor Controllers and contactors for non-motor loads
IEC/EN 60947-5-1	Low-Voltage Switchgear and Controlgear – Part 5-1: Control circuit devices and switching elements – Electromechanical control circuit devices
IEC/EN 60947-5-2	Low-Voltage Switchgear and Controlgear – Part 5-2: Control circuit devices and switching elements – Proximity Switches
IEC/EN 60947-7-1	UL Standard for Safety Low-Voltage Switchgear and Controlgear – Part 7-1: Ancillary equipment – Terminal Blocks for copper conductors
IEC/EN 60947-7-2	UL Standard for Safety Low-Voltage Switchgear and Controlgear – Part 7-2: Ancillary Equipment – Protective Conductor Terminal Blocks for Copper Conductors
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IEC/EN 61010-1	Safety requirements for electrical equipment for measurement, control, and laboratory use - part 1: general requirements
IEC/EN 61010-1+AMD1	Safety requirements for electrical equipment for measurement, control, and laboratory use - part 1: general requirements
IEC/EN 61010-2-101	Safety requirements for electrical equipment for measurement, control and laboratory use - part 2-101: particular requirements for in vitro diagnostic (IVD) medical equipment
IEC/EN 61010-2-201	Safety requirements for electrical equipment for measurement, control, and laboratory use - part 2-201: particular requirements for control equipment
IEC/EN 62304	Medical device software - software life cycle processes
IEC/EN 62304+AMD1	Medical device software - software life cycle processes
IEC/EN 62368-1	Audio/video, information and communication technology equipment - part 1: safety requirements
UL 486A-486B	UL Standard for Safety Wire Connectors
UL 486C	UL Standard for Safety Splicing Wire Connectors
UL 508	Industrial Control Equipment
UL 1054	UL Standard for Safety Special-Use Switches
UL 1059	UL standard for Safety Terminal Blocks
UL 60065	Standard for audio, video and similar electronic apparatus - safety requirements
UL 60601-1	Medical electrical equipment, part 1: general requirements for safety
UL 60947-1	UL Standard for Safety Low-Voltage Switchgear and Controlgear – Part 1: General Rules
UL 60947-4-1	UL Standard for Safety Low-Voltage Switchgear and Controlgear – Part 4-1: Contactors and motor-starters-Electromechanical contactors and motor starters

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UL 60947-5-2	UL Standard for Safety Low-Voltage Switchgear and Controlgear – Part 5-2: Control circuit devices and switching elements – Proximity Switches
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